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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/559,542	04/28/00	BLUME	R 065910.0102

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BROBECK, PHLEGER & HARRISON, LLP
ATTN: INTELLECTUAL PROPERTY DEPARTMENT
1333 H STREET, N.W. SUITE 800
WASHINGTON DC 20005

EXAMINER

EVANS, C

ART UNIT	PAPER NUMBER
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1615

DATE MAILED:

05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/559,542

Applicant(s)

BLUME ET AL.

Examiner

Charesse L. Evans

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Claims 1-32 are pending in this action.

Claim Objections

Claim 5 is objected to because of the following informalities: Claim 5 improperly refers to claim 4. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al. (US 4,756,911) in view of Dansereau et al. (US 5,032,406). The claims are directed to a sustained released formulation of guaifenesin. The formulation may comprise a hydrophilic polymer and a water-insoluble polymer.

Drost teaches a controlled release tablet comprising a medicament and a coating or film layer formed of a mixture of hydrophilic polymer film-formers and a relatively water-insoluble hydrophobic polymeric barrier material (column 7, lines 14-21). The polymers used in the

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referenced invention include methylcellulose, hydroxypropylmethylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, and hydroxypropyl methylcellulose phthalate (column 7, lines 27-42). The referenced invention further comprises ingredients such as lactose, sugar, mannitol, sorbitol, magnesium stearate, stearic acid and calcium stearate (column 6, line 65 through column 7, line 4). Drost does not expressly teach guaifenesin, but bronchodilators, the therapeutic category to which it belongs, is taught (column 4, line 58).

Drost does not expressly teach a bi-layer tablet, however Dansereau teaches a dual-action tablet comprising an outer tablet and an inner tablet where the active ingredient in both layers is guaifenesin (column 3, lines 4-18).

Neither Drost or Dansereau expressly teaches an acrylic resin, however it is the position of the examiner that the acrylic resin does not impart a patentable difference. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ2d 1302, 1303 (PTO Bd.Pat.App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd.Pat.App. & Int.) and *In re Best*, 562 F.2d. 1252, 195 USPQ 430 (CCPA 1977).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Drost so as to include the multiple layer tablet construction as taught in Dansereau. One having ordinary skill in the art would have been motivated to make such a modification to increase the efficacy of active ingredients which have half lives of less than two hours and which experience decreased absorption efficiency in the lower gastrointestinal tract.

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Therefore, the claimed invention as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as every element of the invention has been taught by the collective teachings of the references.

Conclusion

No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Cuca et al. (US 5,494,681) discloses tastemasked pharmaceutical materials; and
- Khan et al. (US 5,656,296) discloses dual control sustained release drug delivery systems and methods for preparing the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on M-F 7:00am - 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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May 2, 2001

THURMAN K. PAGE
SUPERVISORY/PATENT EXAMINER
TECHNOLOGY CENTER 1600